REMARKS

The Office Action of February 5, 2009 presents the examination of claims 1-4, 7-9 and 11-13, claims 5, 6 and 10 having been previously canceled. New claims 14 and 15 are added for examination.

The present paper amends claims 1 and 4 to clarify that 1α, 25-dihydroxy vitamin D and 25-hydroxy vitamin D are the analytes. Claim 1 is further amended to recite "active" method steps to conform it to U.S. practices.

New claims 14 and 15 find support in the specification at least in the working example 9; see, p. 34, lines 17 ff. See also, page 17, lines 26 and following.

Rejection under 35 USC § 112, second paragraph

Claims 1-4, 7-9 and 11-13 are rejected under 35 USC § 112, second paragraph for allegedly being indefinite for the several reasons set forth in paragraphs 4 and 5 of the Office Action. Applicants submit that the amendments to claims 1 and 4 obviate this rejection.

Rejection under 35 USC § 112, first paragraph

Claims 1-3 and 11-13 are rejected under 35 USC § 112, first paragraph, for alleged lack of enablement. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner asserts that the claims include determination of 1α, 25-dihydroxy vitamin D in a sample despite a 100- to 1000-fold excess of 25-hydroxy vitamin D in a typical clinical sample. The Examiner admits that the claims are enabled for detection of 1α, 25-dihydroxy vitamin D provided that the 25-dihydroxy vitamin D has been separated from the sample.

Applicants disagree with the Examiner's decision. For instance, at page 17, lines 26 and following, the specification describes that the various methods of the invention can be made specific for the 1α,25-dihydroxy vitamin D compound by use of an antibody or binding protein or receptor that specifically binds to 1α,25-dihydroxy vitamin D.

Nevertheless, to advance the prosecution of the present claims, claims 1 and 4 have been amended to recite that the amount of 1α,25-dihydroxy vitamin D and 25-hydroxy vitamin D is

measured, and claim 14 is added to include a step of removing 25-hydroxy vitamin D from the sample prior to performing the competitive protein binding assay. Applicants submit that the claims thus are of scope commensurate with that deemed enabled by the Examiner and the instant rejection should be withdrawn.

Rejections under 35 USC § 103

Claims 1-4, 7-8 and 11 are rejected under 35 USC § 103(a) as being unpatentable over Holick et al. WO '127. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested. Claim 9 is rejected under 35 USC § 103(a) as being unpatentable over Holick et al. WO '127 in view of DeLuca '770. These rejections are respectfully traversed. Reconsideration and withdrawal thereof are requested.

As Applicants have previously argued, the Examiner fails to establish *prima facie* obviousness of the invention. The compounds synthesized by Holick '127 as the displacement ligand (corresponding to the "vitamin D derivative of formula (I)" in the present claims) are distinct from the vitamin D derivative of formula (I) of the instant invention. Furthermore, Holick's displacement ligands demonstrate a displacement efficiency approximately 1/11 that of the present compounds of formula (I) now claimed.

The Examiner has tried to explain that Holick WO '127 does actually make the displacement ligand of the present invention or one very similar to it. But, the Examiner has never explained how, if the compound of Holick WO '127 is so similar to that of the present invention, so much lower a displacement efficiency is seen. Instead, the Examiner simply dismisses the experimental results presented in Holick WO '127 and asserts that similar compounds are expected to show similar experimental effects.

Applicants submit that it is improper for the Examiner to ignore this discrepancy in his reasoning. That is, if indeed Holick's compounds are similar to those of formula (I) in the present claims, then they should show the same displacement efficiency, not displacement efficiency 1/11 that observed for the compounds of formula (I).

Applicants stand by their explanations of differences between the present invention and the prior art and their arguments made previously. The rejections of claims 1-4, 7-9 and 11 should be withdrawn.

Rejection based on non-statutory double patenting

Claims 1-4, 7-8 and 11-13 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-5 of US 6787660 in view of Holick WO '127.

Applicants request that this issue be held in abeyance; Applicants will address this issue by filing a Terminal Disclaimer upon a decision by the Examiner that all of the remaining reasons for rejection have been overcome.

Applicants assert that the pending application is in condition for allowance. The favorable actions of withdrawal of the pending rejections and issuance of the claims are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell Reg. No. 36,623 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: August 5, 2009

Respectfully submitted,

By _____

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